

In the Drawings:

The attached sheet of drawings includes changes to FIG. 2.

Attachment: Replacement sheet

REMARKS

Applicants have amended the specification to capitalize the trademarks TEFLON and DACRON and to insert the names of the compounds represented by these trademarks. Other terms, for example, "Tenckhoff catheter," are descriptive names commonly used in this field and are not trademarks. Applicants have also provided a new Title and abstract as requested by the Examiner and have further amended the specification to overcome the objections in paragraph 4 of the Action. The replacement of the original claims above moots the objections in paragraph 5 and the rejection in paragraph 6 of the Action. Applicants have taken the Examiner's helpful comments into account in drafting the new claims.

Applicants advise that the new claims are supported at least in the following paragraphs in the specification:

Claim 35: [0013], [0059], [0060] and [0075].

Claim 36: [0016], [0072], and [0074] through [0076].

Claim 37: [0018], [0072] and [0111].

Claim 38: [018], [0078] and [0111].

Claim 39: [0080].

Claim 40: [0062], [0106], [0114] and [0212].

Claim 41: [0016] - [0020], [0066], [0067], [0069] - [00072], [0078], [0090] and [0098].

Claim 42: [0016] - [0020], [0059], [0066], [0067], [0069] - [0071], [0078] and [0102].

Claim 43: 0023], [0046], [0047], [0102], [0105], [0120], [0132] and [0137].

Claim 44: [0102] and [0106].

Claim 45: [0015], [0018], [0019], [0060], [0061], [0066], [0069], [0070], [0074], [0075] and [0082].

Claim 46: [0059] [0061], [0062], [0065], [0073], [0076], [0082], [0101], [0103] and [0105].

Claim 47: [0063], [0064], [0066], [0071], [0072], [0100], [0147] and [0211].

Claim 48: [0061], [0062], [0065], [0073], [0076], [0082], [0101], [0103], [0105] - [0107], [0110], [0111], [0113], [0115] and [0120].

Claim 49: [0059], [0061], [0065], [0070], [0108], [0110] and [0179].

Claim 50: [0178], [0212] and [0214].

Claim 51: [0108] and [0221].

Claim 52: [0029], [0050] - [0053], [0072], [0079], [0081], [0085], [0089], [0103], [0111] and [0116].

Claim 53: [0115] and in original claim 23.

Claim 54: [0020], [0053], [0081], [0082], [0090] and [0097].

Claim 55: [0214], [0219] and [0222] and in original claim 33.

Claim 56: [0021].

Entry of new claims 35-56 is respectfully requested.

Claims 1-16, 18, 20, 21 and 27-30 stand rejected as anticipated by Sparks. This rejection is respectfully traversed in view of the new claims, to which Sparks is not relevant.

The Sparks reference cited by the Examiner refers to the Sparks mandrel prosthesis. The Sparks mandrel prosthesis is made of cells derived from connective tissue. However, the graft material of this invention comprises non-vascularized tissue derived from cells of the bone marrow that have entered a body cavity. The connective tissue of the Sparks mandrel prosthesis was found not to develop elastin nor differentiating to smooth muscle post-implantation. This verifies that the Sparks mandrel prosthesis tissue is a clearly different phenotype from a non-vascularized tissue of the present invention. As discussed in paragraph [0059] of the present application, the non-vascularized tissue comprises non-thrombogenic, mesothelial cells overlying several layers of myofibroblasts. After grafting, elastic fibres are produced by the myofibroblasts. Thus, the non-vascularized tissue of the present invention has a different

composition to that of the Sparks mandrel prosthesis, so Sparks cannot anticipate the new claims in this application.

Applicants note that there is a fundamental difference between a tissue generated around the molding in the body cavity of this invention as compared to the tissue obtained by placing the Sparks mandrel prosthesis intramuscularly near the rib cage. The non-vascularized tissue of this invention comprises relatively young cells that can divide at any time. By contrast, the fibroblasts generated on the Sparks prosthesis have limited life span. Therefore, in an older subject, the tissue generated by the Sparks prosthesis would be unlikely to be suitable to generate a suitable blood vessel and thus would not perform the method claimed.

Additionally, the tissue generated in accordance with the method of this invention is non-vascularized prior to grafting even though it may be used in a vascular tissue graft. Non-vascularized tissue forms in part due to the fact that the molding is free floating within a body cavity such as the peritoneal. If adherence occurs it is likely that blood vessels would form and the tissue would become vascularized. The method of Sparks necessarily generates vascularized tissue due to its connectivity to surrounding tissue, as it is not free floating within a body cavity.

Thus, applicants respectfully submit that the subject matter of the newly added claims is novel over Sparks and respectfully request the Examiner to reconsider and withdraw this rejection.

Claims 31-34 stand rejected as anticipated by Moukheibir. This rejection is mooted by the cancellation of these claims.

Claims 22-26 stand rejected under 35 USC 103(a) on Sparks in view of Winston. Applicants respectfully submit that this rejection is not applicable to the newly added claims. This is because Sparks, even in combination with Winston, fails to teach or reasonably suggest a method of producing a tissue by placing a molding support within a body cavity for a time and under conditions sufficient for non-vascularized tissue comprising myofibroblasts to form on the

molding support. At best, the combination of Sparks and Winston would have motivated a person skilled in the art to produce vascularized tissue by implanting a molding support (*i.e.*, Sparks mandrel prosthesis) intramuscularly near the rib cage and cryogenically freezing the vascularized tissue, wherein the tissue so produced lacks myofibroblasts. Thus, the combination of Sparks and Winston fails to teach and would not reasonably have suggested the features of the new claims.

Claims 17 and 22 stand rejected under 35 USC 103(a) on Sparks alone. The Examiner asserts in support of this rejection that although Sparks does not expressly disclose that the molding support is a biodegradable matrix, it would have been obvious to a person of ordinary skill in the art to have the molding made from a biodegradable matrix, allegedly because applicants have not disclosed that the specified molding support material provides an advantage or solves a stated problem over TEFLON as disclosed by Sparks. Applicants respectfully disagree. As noted above, Sparks neither teaches nor suggests the step of placing a molding support within a body cavity for a time and under conditions sufficient for non-vascularized tissue comprising myofibroblasts to form on the molding support. At best, Sparks discloses a method of introducing a molding support intramuscularly to form vascularized tissue that lacks myofibroblasts. As such, Sparks fails to teach or reasonably suggest each and every feature of the newly added claims and consequently, the Examiner is respectfully urged to reconsider and withdraw this rejection.

The Examiner has rejected claims 18 and 19 for obviousness-type double patenting. The cancellation of claims 18 and 19 moots this rejection.

In view of the above, early action allowing claims 35-56 is solicited.

In the event the Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in

Application No.: 10/628,308

Attorney Docket No.: 229752001220

connection with the filing of this document to **Deposit Account No. 03-1952** referencing
Attorney Docket No. **229752001220**.

Dated: June 16, 2006

Respectfully submitted,

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